DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 4, 2015

Guangdong Intmed Medical Appliance Co., Ltd.
Mr. Sanfei Wang
Management Representative
1# South Shunhe Road Europe Industry Park
Shunde District, Foshan
Guangdong 528300
CHINA

Re: K143497
Trade/Device Name: Safety Auto-Disable Syringe with Needle (Auto-Lock)
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG, FMF, FMI
Dated: September 23, 2015
Received: October 5, 2015

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143497

Device Name
Safety Auto-Disable Syringe with Needle (Auto-Lock)

Indications for Use *(Describe)*
The Safety Auto-Disable Syringe with Needle (Auto-Lock) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin except phlebotomy.

It has a detachable needle with a dedicated fitting. The Safety Auto-Disable Syringe with Needle (Auto-Lock) contains an inner mechanism used to allow the needle to be retracted inside the plunger rod of the syringe after the operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

K143497

510(k) Summary

Submitter: Guangdong Intmed Medical Application Co., Ltd
1# South Shunhe Road Europe Industry Park, Shunde District, Foshan, Guangdong, P.R. China, 528300

Contact: Mr. Wang, Sanfei Management Representative
Phone: (86)18616806984
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Date Prepared: Sep. 23, 2015

Device Trade Name: Safety Auto-Disable Syringe with Needle (Auto-Lock)

Device Common Name: Safety Syringe (with Needle)

Class: II

Classification Name: 880.5860 Piston Syringe

Product Code: MEG, FMI, FMF

1. Predicate Device (Primary Predicate Device):

Device	Company	Product Code	510(k) Number
WTF Secura Safety Syringe (with Needle)	Beijing WanTeFu Medical Apparatus Co., Ltd	MEG, FMF, and FMI	K132120

2. Reference Predicate Devices:

Device	Company	Product Code	510(k) Number
BD Spring Based Syringe	BD Medical	MEG and FMF	K011103
BD Integra 1ml Syringe	BD Medical Surgical	MEG and FMF	K023752

3. Indications for Use:

The Safety Auto-Disable Syringe with Needle (Auto-Lock) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin except phlebotomy.
It has a detachable needle with a dedicated fitting. The Safety Auto-Disable Syringe with Needle (Auto-Lock) contains an inner mechanism used to allow the needle to be retracted inside the plunger rod of the syringe after the operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

3. Product Description:

It has a detachable needle with a dedicated fitting. The Safety Auto-Disable Syringe with Needle (Auto-Lock) contains an inner mechanism used to allow the needle to be retracted inside the plunger rod of the syringe after the operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

The proposed device is a single use, sterile syringe composed of barrel, plunger, plunger, push-button, spring, spring holder, rubber stopper, needle cap, and auto-disable part.

Product Specification

Specification								
Size / Volume	28G (0.36x12mm)	27G (0.4x12mm)	26G (0.45x16mm)	25G (0.5x16mm)	24G (0.55x25mm)	23G (0.6x32mm)	22G (0.7x38mm)	21G (0.8x38mm)
1ml	●	●	●	●				
3ml				●	●	●	●	
5ml				●		●	●	●
10ml						●	●	●
Color of needle hub	Blue-Green	Gray	Brown	Orange	Purple	Blue	Black	Green

Note: the part of size include both external diameter and needle length and in unit of mm

4. Summary of Technology Characteristics and Performance Testing:

The intended use and technology characteristics of the proposed Safety Auto-Disable Syringe with Needle (Auto-Lock), and the substantial equivalence to the predicate device have been demonstrated via data collected in design verifications, clinical simulation investigation and clinical investigation performed in China per the requirements of China FDA. The results of these tests and clinical report provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
No new performance issues were raised during the testing. All materials used in the proposed device meet the requirements of ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process, same as predicate devices.

Below is a list of non-clinical performance data completed for the proposed device:

Bench Testing	**Bench Testing(continued)**	**Biocompatibility/In vivo testing**
Sterile test	Needle point piecing strength test	In vitro cytotoxicity (ISO Elution)
Bacterial Endotoxin test	Piston in barrel fitness test	Irritation (Intracutaneous Reaction)
Residual of EO test	Tolerance on graduated capacity(delivery accuracy) test	Sensitization (ISO Guinea Pig Maximization)
Springe holder deactivating test	Dead space test	Hemolysis in vitro
Auto-disable part activating strength test	Binding strength between Needle hub & Sheath	Acute systemic toxicity
Auto-disable part resisting force test	Freedom from leakage at needle hub & syringe nozzle	
Binding strength between auto-disable part and needle tube test	Liquid and air leakage past piston	
Force to unplug push button test	Nozzle conical fitting tests	

Also we have packaging testing non-clinical performance data including packaging sealing strength test, and package integrity test.

The subject product, Safety Auto-Disable Syringe with Needle, was compared with the primary predicate device, WTF Secura Syringe (with needle) K132120, and reference predicate devices, BD Spring Based Syringe K011103, and BD Integra 1ml Syringe K023752, using following criteria following the suggestion from “Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes”:

ELEMENT OF COMPARISON	SUBJECT DEVICE	(Primary) Predicate Device	Reference Predicate Devices	
		K132120	Device 1 (K011103)	Device 2 (K023752)
		WTF Secura Syringe (with needle)	BD Spring Based Syringe	The BD IntegraTM Syringe
Indications for Use	The Safety Auto-Disable Syringe with Needle (Auto-Lock) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin except phlebotomy. It has a detachable needle with a dedicated fitting. The Safety Auto-Disable Syringe with Needle (Auto-Lock) contains an inner mechanism used to allow the needle to be retracted inside the plunger rod of the syringe after the operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.	The WTF Secura Syringe (with needle) is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. The WTF Secura Syringe(with needle) has a manually attached WTF Secura Retracting Needle. The WTF Secura Syringe (with needle) contains an inner mechanism used to allow the WTF Secura Retracting Neelde to be retracted inside the plunger rod of the syringe when operator's thumb force released. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/ syringe combination	BD Spring Based Syringe is used for general purpose injection and aspiration of fluid from vials, ampoules and part of the body below the surface of the skin except phlebotomy. The BD Spring Based Syringe has a detachable needle with a dedicated fitting. The dedicated interface prevents clinician from attaching BD Spring Based Syringe components to a standard syringe or needle. The BD Spring Based Syringe contains a tool used to cut through the stopper and inner hub allowing the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposable of the used needle / syringe combination.	The BD Integra™ Syringe is used for aspiration of fluids from vials and ampoules and a variety of fluid injections below the surface of the skin. It is not intended to be used for phlebotomy. The insulin syringe has scale lines in insulin units and is used for insulin injections. The tuberculin syringe can be used for any of the 3 types of common injections (intra-dermal, intra-muscular or subcutaneous). The BD Integra™ Iml Syringe has a permanently attached needle. The BD Integra™ 1 nil Syringe contains a tool used to cut through the hub and stopper allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.
	Brief Summary: The subject device has smaller intended application scope compare to WTF Secura Safety Syringe since subject device is not used for phlebotomy, and smaller intended application scope compare to BD Integra 1m syringe since subject device is not used for insulin injection.			

ELEMENT OF COMPARISON	SUBJECT DEVICE	(Primary) Predicate Device	Reference Predicate Devices	
		K132120	Device 1 (K011103)	Device 2 (K023752)
		WTF Secura Syringe (with needle)	BD Spring Based Syringe	The BD IntegraTM Syringe
syringe type	Plunger, anti-stick with hypodermic needle	Plunger, anti-stick with hypodermic needle	Plunger, anti-stick with hypodermic needle	Plunger, anti-stick with hypodermic needle
Safety Features	Active safety feature, manually activated by user	Active safety feature, manually activated by user	Active safety feature, manually activated by user	Active safety feature, manually activated by user
tip type	Tri-Beveled Tip	Tri-Beveled Tip	Tri-Beveled Tip	Tri-Beveled Tip
volume	1 / 3/ 5 / 10 ml	1/ 2.5/ 3 /5 /10 ml	3 ~10 ml	1ml
needle length	Tolerances on length comply to ISO 7864	Tolerances on length comply to ISO 7864	Tolerances on length comply to ISO 7864	Tolerances on length comply to ISO 7864
needle gauge	21G~28G	21/ 22/ 23/25/30 G	18G ~ 25 G	25G ~ 30 G
needle tip configuration	15 oC regular point	15 oC regular point	15 oC regular point	15 oC regular point
nozzle type	Needle hub Luer connector; Needle & syringe separable	Needle hub Luer connector; Needle & syringe separable	Needle hub Locking-fit; Needle & syringe separable	Needle hub Locking-fit; Needle & syringe not separable
barrel marking specs	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1
gradations legibility	Legible according to ISO 7886-1	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1	Scales as required by ISO 7886-1
needle cover dimensions	Traditional Cover comply to ISO 7864	Traditional Cover comply to ISO 7864	Traditional Cover comply to ISO 7864	Traditional Cover comply to ISO 7864
needle cover color	Colorless according to ISO 7864	Colorless according to ISO 7864	Colorless according to ISO 7864	Colorless according to ISO 7864
lubricant amount	Comply ISO 7864 & ISO 7886-1	Comply ISO 7864 & ISO 7886-1	Comply ISO 7864 & ISO 7886-1	Comply ISO 7864 & ISO 7886-1
barrel transparency	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1	Clear as required by ISO 7886-1
delivery accuracy/ Capacity Tolerance	Comply to ISO 7886-1	Comply to ISO 7886-1	Comply to ISO 7886-1	Comply to ISO 7886-1
reuse durability	Can't re-used according to ISO 7886-4	Can't re-used according to ISO 7886-4	Can't re-used according to ISO 7886-4	Can't re-used according to ISO 7886-4
hub/needle bond strength	Conform to ISO 7864	Conform to ISO 7864	Conform to ISO 7864	Conform to ISO 7864

ELEMENT OF COMPARISON	SUBJECT DEVICE	(Primary) Predicate Device	Reference Predicate Devices	
		K132120	Device 1 (K011103)	Device 2 (K023752)
		WTF Secura Syringe (with needle)	BD Spring Based Syringe	The BD IntegraTM Syringe
Primary package barrier	Sterile barrier of primary package according ISO 11607-1/-2	Sterile barrier of primary package according ISO 11607-1/-2	Sterile barrier of primary package according ISO 11607-1/-2	Sterile barrier of primary package according ISO 11607-1/-2
Re-used prevention features	Conform to ISO 7886-4, and FDA guidance, Submission for Medical Device with Sharps Injury Prevention Features	Conform to ISO 7886-4 (Not clear the result of this FDA guidance)	Conform to ISO 7886-4 (Not clear the result of this FDA guidance)	Conform to ISO 7886-4 (Not clear the result of this FDA guidance)
Materials:				
Barrel	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Plunger	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Piston	Isoprene rubber	Isoprene rubber	Isoprene rubber	Isoprene rubber
Needle Hub	Polypropylene	Polypropylene	Polypropylene	Polypropylene
Needle	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Needle Sheath	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Lubricant	PDMS	Un-identified	Un-identified	Un-identified
O Ring	Silicone rubber	Silicone rubber	Silicone rubber	Silicone rubber
Biocompatibility	Conforms to ISO10993	Conforms to ISO10993	Conforms to ISO10993	Conforms to ISO10993
Performance	Conforms to ISO 7864, ISO 7886-1, ISO 7886-4	Conforms to ISO 7864, ISO 7886-1, ISO 7886-4	Conforms to ISO 7864, ISO 7886-1, ISO 7886-4	Conforms to ISO 7864, ISO 7886-1, ISO 7886-4
labeling	Conform to ISO 7886, ISO 7886-1, ISO 7886-4, and 21 CFR Part 801	Conform to ISO 7886, ISO 7886-1, ISO 7886-4, and 21 CFR Part 801	Conform to ISO 7886, ISO 7886-1, ISO 7886-4, and 21 CFR Part 801	Conform to ISO 7886, ISO 7886-1, ISO 7886-4, and 21 CFR Part 801
Sterilization level and method	SAL 10-6 EO sterilization according to ISO 11135	SAL 10-6 EO sterilization according to ISO 11135	SAL 10-6 EO sterilization according to ISO 11135; Gamma sterilization	SAL 10-6 EO sterilization according to ISO 11135; Gamma sterilization

Comparison Summary	The subject device has the same or simpler intended use comparing to predicate devices. The subject device has similar operation principle comparing to predicate devices. Except for BD Integra 1ml syringe (not separable), all devices have a detachable needle with a dedicated luer fitting. The key difference between the proposed and predicate devices are the applied syringe volumes and needle gauges have some differences. The proposed device has product volumes as 1 / 3/ 5 / 10 ml, comparing to WTF secura safety syringe's product volumes as 1/ 2.5/ 3 /5 /10 ml. And the proposed device has product needle gauges range as 21G – 28G, comparing BD spring based syringe & Integra 1ml syringe's product needle gauges 18G – 30G. Another different is the sterilization method. For both our proposed device and WTF secura safety syringe, only EO sterilization method is applied. However for BD spring based syringe, Gamma irradiation sterilization method can be applied too. However, this sterilization method non-identical will not impact to both proposed and predicate devices since relevant International ISO sterilization standards are followed to ensure the sterilization process to product. These differences do not have impact to product technology & performance to both subject and predicate devices, and do not raise new issues of product performance. With the same / smaller intended use scope & similar principle of operation, and complying to the same ISO standards, e.g. ISO 7886, ISO 7886-1, ISO 7886-4, and 21 CFR Part 801, and FDA guidance, Submission for Medical Device with Sharps Injury Prevention Features, the proposed device, Intmed safety auto-disable syringe with needle, performs in a similar manner to the predicate devices, WTF Secura Syringe (with needle), BD Spring Based Syringe, and BD Integra 1ml Syringe All these test / comparison have corresponding requirements/ control criteria following above mentioned standards. And the test results and comparison results show that the subject product is substantially equivalent to the predicate device in performance.

5. Simulated Clinical Study Summary:

Following the 'Guidance for Industry and FDA Staff- Medical Devices with Sharps Injury Prevention Features' (Aug., 9, 2005), the Intmed Safety Auto-Disable Syringe with Needle (Auto-Lock) had evaluated by simulated clinical study. During the simulated clinical study, there were no failures observed in a trial test run of 512 devices, we would be 97.5% confident that the true failure rate was no higher than 0.7% and 99.5% confident that it was no higher than 1.1%.

6. Conclusion:

Based on the intended use, technology characteristics, and performance testing, the proposed product, safety auto-disable syringe, has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate device.